REMARKS

Claims 1-15 and 17-21 are pending herein. Claim 17-21 have been withdrawn from consideration.

Initially, the Applicant thanks Examiner Angell for extending the courtesies to him and his undersigned attorney during a personal interview on September 14, 2007. The substance of the points discussed in the interview is provided below.

In the interview, the rejections of Claims 1-15 under 35 U.S.C. §102(b) over Thulé et al. (Diabetes, May 1999, supplement) as evidenced by Thulé and Liu presentation at the ADA 59th Annual Meeting, June 1999, and Vaulont et al. and Goswami et al. publications, ii) Thulé et al. (Abstract from Meeting June 9-13, 1999) as evidenced by Thulé and Liu presentation at the American Society of Gene Therapy, 2nd Annual Meeting, June 1999, and Vaulont et al. and Goswami et al publications, and iii) Thulé et al. (Abstract from Meeting of June 1998) as evidenced by Thulé and Liu presentation at the ADA 58th Annual Meeting, June 1998, and Vaulont et al. and Goswami et al. publications, were all discussed.

In the interview, Examiner Angell clarified that the term "as evidenced by" used in formulating his first rejection (set forth on page 2 of the Office Action), means that the Thulé (Diabetes) abstract is the same as Thulé and Liu presentation at the ADA 59th Annual Meeting, June 1999. Likewise, the term "as evidenced by" in the second rejection (set forth on Page 5 of the Office Action) means that the

Thulé et al. abstract from June 9-13, 1999, meeting is the same as the Thulé and Liu presentation at the American Society of Gene Therapy, 2nd Annual Meeting, June 1999. And, the term "as evidenced by" used in formulating his third rejection (set forth on Page 7 of the Office Action) means that the Thulé et al. abstract from June 1998 meeting, is the same as the Thulé and Liu presentation at the ADA 58th Annual Meeting, June 1998.

Examiner Angell further clarified that the word "not" was missing from the first sentence, in the fourth full paragraph, on Page 9 of the Office Action. In other words, he acknowledges that Thulé abstract do not explicitly disclose the sequences of Claim 9.

In the "Response to Arguments" section, on Page 9 of the Office Action, although the Examiner acknowledged that the Thulé abstracts do not explicitly disclose the sequences of Claim 9, he stated the following:

> However, considering the information which applicants have provided in the 3/14/2006 IDS, it is clear that the presentations given by the Inventor, which are the presentations associated with the cited abstracts, disclosed sufficient information which allow one of ordinary skill art to construct the claimed vector. Specifically, the presentations disclosed the exact regions of nucleotide sequences used to construct the elements which are the sequences of claim 9. Furthermore, as evidenced by Vaulont et al. and Goswami et al. the exact nucleotide sequences disclosed by Thule could be constructed without knowledge of the Applicant's disclosure. Therefore, Applicants arguments are not persuasive. (emphasis added)

From the above and the Office Action, it is clear that the various Thulé abstracts do not disclose the sequences of Claim 9. It is also clear from above and the Office Action that the Examiner is relying on the presentations given by the inventor to supplement the deficiencies of the various Thulé abstracts. It is further noted from the Office Action, without admission, that Vaulont et al. and Goswami et al. publications arguably merely disclose, at most, individual elements of the present invention.

It is further clear from the Office Action that the Examiner has relied on the Thulé abstracts, the presentations, and Vaulont et al. and Goswami et al. to combine in some manner to conclude that these provided "an enabling disclosure which teaches the claimed invention." Based on these documents and the presentations, the Examiner concluded that the claimed invention was described in a printed publication in this country more than one year prior to the date of application for patent in the United States.

It is respectfully submitted that anticipation under 35 U.S.C. §102(b) requires the disclosure in a single prior art reference of each element of the claim under consideration. W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983) (citing Soundscriber Corp. v. United States, 360 F.2d 954, 960, 148 USPQ 298, 301 (Ct. Cl.), *adopted*, 149 USPQ 640 (Ct. Cl. 1966), *cert., denied*, 469 U.S. 851 (1984). *See also* Carella v. Starlight Archery, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir.), *modified on reh'g*, 1 USPQ2d 1209 (Fed. Cir.

1986); RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984).

Further, the single prior art reference must disclose each element of the claimed invention "arranged as in the claim." Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing Connell v. Sears, Roebuck & Co., 772 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983). In other words, even if the single prior art reference includes all the claimed elements, if the arrangement of the elements is different from the prior art arrangement, anticipation will not be present.

As noted above, the Examiner is relying not on a single reference, but multiple publications and presentations in support of his anticipation rejections. None of the cited abstracts or publications teach or suggest the claimed invention. Therefore, it is respectfully submitted that Claims 1-15 are not anticipated by any of the Thulé publications or Vaulont et al. and Goswami et al. publications.

With respect to the Examiner's reliance on the presentations, it is respectfully submitted that the PowerPoint presentations are not "printed publications" for the purposes of 35 U.S.C. §102(b).

The Federal Circuit in In re Klopfenstein affirmed that a presentation that includes a transient display of slides is not necessarily a printed publication. 380 F.3d 1345, 1349 & n.4 72 U.S.P.Q.2d 1117, 1120m4 (Fed. Cir. 2004). The

court further noted:

> While *Howmedica* is not binding on this court, it stands for the important proposition that the mere presentation of slides accompanying an oral presentation at a professional conference is not per se a "printed publication" for the purposes of §102(b). (emphasis added)

It is respectfully submitted that each of the presentations relied on by the Examiner, was for a very short duration, i.e., about ten minutes, and included PowerPoint presentations of 17, 24, and 30 slides. Copies of the slides were not distributed or later indexed in any database, catalog or library. In other words, each presentation was of a highly transient nature. Further, the information displayed in the presentations was of a highly complex nature requiring familiarity and high degree of expertise to understand, retain and capture the relevance adequate enough for later reproduction. Therefore, it is respectfully submitted that none of the presentations relied on by the Examiner qualifies as printed publication for the purposes of 35 U.S.C. §102(b).

In the Office Action, the Examiner notes various nucleotide numbering and states that the slides indicate the exact nucleotides of rat promoter elements used to construct the claimed vector. It is submitted that the numbers presented in the slides are ambiguous, and non-enabling to one skilled in the art. The numbers referring to bases or base pairs in genetic sequence data are only interpretable

when combined with a referenced origin. An origin or referenced start of numbering was not provided in the presentations. The sequence numbers provided are, therefore, non-specific and ambiguous.

In this regard, it is noted that the inventor has been unable to discover an accepted, authorized nomenclature for DNA sequence numbering. The Web page for the nomenclature committee of the International Union of Biochemistry and Molecular Biology provides no guidance. The world's largest genetic sequence data bases, NCBI/GenBank, European Molecular Biology Laboratory-Nucleotide Sequence Database, and the DNA Data Bank of Japan, number sequences as entered, beginning with 1, irrespective of function or structure. The Rat Genome Database refers to these databases. COMPEL, a database of composite regulatory elements affecting gene transcription in eukaryotes allows description of the alternative reference origins for numbering sequences, but does not contain entries for either rat insulin-like growth factor binding protein-1 (IGFBP-1) or pyruvate kinase.

Further, in scientific publications dealing with a single gene, sequence numbers are often referenced to either the transcription initiation site, or the translation initiation site. However, publications dealing with the same or similar sequences are inconsistent with respect to which reference site they utilize. Unterman et al. (copy enclosed) number the published sequence of the rat IGFBP-1

promoter beginning with the translation start site. In a later publication, these same authors number the same sequence beginning with the transcription start site (Goswami et al. - of record). Similarly, Cognet et al. (of record) initiate promoter sequence numbering for the rat liver pyruvate kinase (L-PK) promoter from the transcription start site, while Inoue et al. (copy enclosed) utilize the translation start.

Across publications, the numbering of similar sequence bases is inaccurate. For example, in Yamada et al. (copy enclosed), the L-PK promoter base designated as -126 is identified as -124 in Cognet et al. Even within a single publication, sequence numbering is inaccurate. In Goswami et al. base number -110 in Figure 3, corresponds to base number -109 in Figure 7. In Unterman et al. (copy enclosed) the base indicated as -109 in Figure 4, is referred to as -116 in Material and Methods.

Further, accounting for differences with respect to which start site is chosen and reported, sequences falling with numeric ranges fail to match across publications. The rat L-PK promoter sequences beginning with -1 in Inoue et al. do not match the promoter bases presented in Cognet et al. Similarly, the bases designated by the numbers -149- -146 of L-II in Table 1 of Yamada et al. are without correlation in the sequence offered by Cognet et al.

Moreover, it is submitted that the numbers presented in the slides do not correlate with the claimed sequences. For instance, the numbers for the IGFBP-1

sequences indicate that the $(GIRE)_3$BP-1 promoter includes bases -111 to 96+ of IGFBP-1. However, the sequence in SEQ ID NO: 5 of the invention, encompasses bases best indicated by base numbers -114 to +105 of the IGFBP-1 promoter with respect to the transcription start site. Likewise, the L-PK promoter sequence numbers presented, -173 to -125, also do not correlate. SEQ ID NO: 5 encompasses three head-to-tail repeats of bases best indicated by base numbers -173 to -123, respective to the transcription start site.

In summary, there exists no standard, accepted numbering system for DNA sequence bases or base pairs with respect to function or replication. The largest most commonly used DNA sequence data bases number entered sequences from 1 onward. All other numberings of DNA sequences must be coupled with a referenced initiation to be useful. Such a reference was not provided in the slide presentations. Published literature referring to both the rat L-PK and rat IGFBP-1 promoters were not uniform in their use of an internal reference, even within authors. Moreover, base numbers in published sequences of rat L-PK and rat IGFBP-1 promoters were inconsistent both within single publications and across publications. Further, published literature is not concordant with respect to promoter sequences, particularly of the rat L-PK promoter. Additionally, the numbers presented in the slides do not correlate with SEQ ID NO: 5. Consequently, the numbers provided in the presentations do not, and could not, accurately and reliably disclose the claimed sequence of SEQ ID NO: 5.

In view of the above, it is respectfully submitted that even if arguendo the presentations could be relied upon, they do not disclose or would enable one of ordinary skill in the art to reconstruct the claimed sequences.

With respect to the Examiner's assertion that the sequences of the present invention could be constructed without knowledge of the Applicant's disclosure, it is respectfully submitted that anticipation based on inherency "...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting Hansgirg v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939) (emphasis in original). In other words, what is missing must necessarily result from the prior art reference.

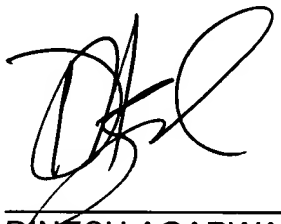
CONCLUSION

In view of the above, it is respectfully submitted that Claims 1-15 and 17-21 are neither anticipated by the Thulé abstracts, the presentations, or Vaulont et al. and Goswami et al. publications. Withdrawal of all the rejections and allowance of these claims are earnestly solicited.

It is believed that no fee is due for this submission. However, should that determination be incorrect, the Commissioner is hereby authorized to charge any deficiencies, or credit any overpayment, to our Deposit Account No. 01-0433, and notify the undersigned in due course.

Should the Examiner have any questions or wish to discuss further this matter, please contact the undersigned at the telephone number provided below.

Respectfully submitted,



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